IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

THE UNITED STATES OF AMERICA,
THE STATE OF ILLINOIS,
THE STATE OF INDIANA,
THE STATE OF IOWA,
THE STATE OF NORTH CAROLINA,
THE STATE OF TENNESSEE,
and
THE STATE OF VIRGINIA, *ex rel.*
June Kimbrough and Scott Steed;

PLAINTIFFS

v.

CIVIL ACTION NO. 3:17CV-277-TBR

ANESTHESIA SERVICES ASSOCIATES, PLLC
d/b/a COMPRENSIVE PAIN SPECIALISTS, STEVEN REID DICKERSON, M.D., JOHN DAVIS, AND JOHN DOES 1-30.

DEFENDANTS

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

COMPLAINT FOR DAMAGES AND OTHER RELIEF
UNDER THE FALSE CLAIMS ACT

JURY TRIAL DEMANDED

I. NATURE OF THE ACTION

1. This is an action by *qui tam* relators June Kimbrough and Scott Steed, in the name of the United States Government, and in the name of the states of Illinios, Indiana, Iowa, North Carolina, Tennessee, and Virginia, to recover penalties and damages arising from Defendants' submissions of false and fraudulent billings to the United States Government, pursuant to the federal False Claims Act ("FCA"), 31 U.S.C. § 3729-32, as amended, and on the state False

Claims Acts enacted in Tennessee, Tenn. Code Ann. §§ 4-18-101 - 4-18-108, *Tennessee False Claims Act* and Tenn. Code Ann. §§ 71-5-181 - 71-5-185, *Tennessee Medicaid False Claims Act*; Illinois, 740 Ill. Comp. Stat. Ann. §§ 175/1 - 175/8, *Illinois False Claims Act*; Indiana, Ind. Code Ann. 5-11-5.5-1 - 5-11-5.5-18, *Indiana False Claims and Whistleblower Protection*; Iowa, Iowa Code Ann. §§ 685.1 - 685.7, *Iowa False Claims Law*; North Carolina, N.C. Gen. Stat. Ann. §§ 1-605 - 1-618, *North Carolina False Claims Act*; and Virginia, Va. Code Ann. §§ 8.01-216.12 - 8.01-216.19, *Virginia Fraud Against Taxpayers Act*, as well as under common law theories of payment by mistake and unjust enrichment.

2. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America and the states of Alabama, Arkansas, Tennessee, Indiana, Illinois, Iowa, Kentucky, Missouri, Mississippi, North Carolina, Ohio and Virginia (collectively "the States"), perpetrated by the Defendants. These claims are based upon Defendants' submission of false and fraudulent patient claims to the United States in order to obtain millions of dollars in payments for various healthcare services from at least 2011 and continuing through the present.

3. These false claims and false statements included Defendants' unlawful scheme to generate millions of dollars in profits by paying kickbacks and illegal remuneration to physicians and nurse practitioners, pursuant to prohibited financial relationships, in violation of the physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), and the Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b).

4. In addition to violating the illegal remuneration aspects of federal law, the Defendants also violated the "reasonable and necessary" aspects of the Medicare and Medicaid reimbursement laws, through, among other methods, the gross abuse of performing and billing

for unnecessary services, including urine drug testing ("UDT"), genetic testing and "health and wellness panels." These claims were false and fraudulent because the tests were non-medically necessary which is a material condition of payment. The false claims arose out of a chronic, serious and knowing scheme through use of false and misleading information to physicians about the need for such testing on all pain management patients in order to induce the ordering of unnecessary testing. Defendants have knowingly submitted many millions of dollars' worth of false claims to the Medicare program for such tests that were not reasonable and necessary, in violation of 42 U.S.C. § 1395y(a)(1)(A).

5. Defendants also violated § 3729(a)(2) of the FCA by making or causing to be made false statements when submitting these claims for payment to Medicare and other government programs. Defendants falsely certified the claims and statements were "true" and/or "correct" and as such were entitled to payment.

6. These acts constitute violations of the FCA and equivalent state statutes, entitling the Plaintiff to civil penalties and damages, as stated herein. Relators are also entitled to a share of the recoveries resulting from this action, pursuant to the statutes cited herein.

II. JURISDICTION

7. Under §3732 of the FCA, this Court has exclusive jurisdiction over the actions brought under the FCA and concurrent jurisdiction over state claims arising from the transactions giving rise to the claims under the FCA. Furthermore, jurisdiction over this action is conferred on this Court by 28 U.S.C. §1331 because this civil action arises under the laws of the United States.

8. Under 28 U.S.C. §136, this Court has supplemental jurisdiction over all other claims set forth in this Complaint because they are so related to the FCA claims that they form part of the same case or controversy.

9. Section 3732(a) of the FCA provides that "any action" under section 3730 may be brought in any judicial district in which a defendant can be found, resides, transacts business, or in which any action proscribed by section 3729 occurred. One or more of the defendants can be found in this judicial district. One or more of the defendants transact business in this judicial district. One or more of the defendants committed acts proscribed by section 3729 in this judicial district.

10. Under the FCA, this complaint is to be filed and remain under seal for a period of at least sixty (60) days and shall not be served on defendants until the Court so orders. The government may elect to intervene and proceed with the action within sixty (60) days after it receives both the complaint and the material evidence and information in support of the complaint.

11. As set forth below, defendants' actions alleged in this Complaint also constitute violations of the *Tennessee False Claims Act*, Tenn. Code Ann. §§ 4-18-101 - 4-18-108, and *Tennessee Medicaid False Claims Act*, Tenn. Code Ann. §§ 71-5-181 - 71-5-185; *Illinois False Claims Act*, 740 Ill. Comp. Stat. Ann. §§ 175/1 - 175/8; *Indiana False Claims and Whistleblower Protection*, Ind. Code Ann. 5-11-5.5-1 - 5-11-5.5-18; *Iowa False Claims Law*, Iowa Code Ann. §§ 685.1 - 685.7; *North Carolina False Claims Act*, N.C. Gen. Stat. Ann. §§ 1-605 - 1-618; and *Virginia Fraud Against Taxpayers Act*, Va. Code Ann. §§ 8.01-216.12 - 8.01-216.19.

12. Based on these provisions, qui tam plaintiffs and relators seek to recover all available damages, civil penalties, and other relief pursuant to the federal and state laws violated by the Defendants.

III. PARTIES TO THE ACTION

13. Qui Tam Plaintiffs June Kimbrough and Scott Steed are citizens and residents of the state of Mississippi.

14. As required under the FCA, 31 U.S.C. § 3730(b)(2), Relators have provided to the Attorney General of the United States and to the United States Attorney for the States of Tennessee, Illinois, Indiana, Iowa, North Carolina, and Virginia, simultaneous with the filing of this complaint, a statement of material evidence and information related to the complaint. This disclosure statement supports the existence of the defendants' false claims.

15. Defendant Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists (hereafter "CPS") is a professional limited liability company organized under the laws of Tennessee, but does, and has done, business through pain management clinics that are operated in at least twelve states: Alabama, Arkansas, Tennessee, Indiana, Illinois, Iowa, Kentucky, Missouri, Mississippi, North Carolina, Ohio and Virginia.

16. Steven Reid Dickerson, MD is the President of CPS and the person identified by Medicare as authorized to apply for NPI modifications and data changes for CPS. Upon information and belief, Dr. Dickerson also holds a significant ownership interest in CPS and/or is otherwise financially related to CPS.

17. Defendant Peter Kroll, MD is a member, owner, founder and medical director of CPS. Upon information and belief, Dr. Kroll also holds a significant ownership interest in CPS and/or is otherwise financially related to CPS.

18. John Davis is the Chief Executive Officer of CPS. Mr. Davis directly recruited CPS physicians and designed the financial relationships and drug screening practices which violated the federal and state laws at issue, as described herein. Upon information and belief, Mr. Davis also holds a significant ownership interest in CPS and/or is otherwise financially related to CPS.

19. John Does 1-30 are those persons who have held ownership interests in CPS from the period 2011-2017, and who directly benefited from the schemes, false claims and violations described herein.

IV. STATUTORY AND REGULATORY BACKGROUND

A. THE FALSE CLAIMS ACT

20. The False Claims Act (FCA) provides, in pertinent part that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;…or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person…
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

B. THE ANTI-KICKBACK STATUTE

21. The Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

22. The Anti-kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. In pertinent part, the statute states:

> (b) Illegal remuneration
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which

payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
(B) to purchase, lease order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

C. THE STARK STATUTE

23. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits an entity providing healthcare items or services from submitting Medicare claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statue) with the entity. The regulations implementing 42 U.S.C. § 1395nn expressly require that any entity collecting payment for a healthcare service performed under a prohibited referral must refund all collected amounts on a timely basis. 42 C.F.R. § 411.353.

24. The Stark Statute establishes the clear rule that the government will not pay for items or services prescribed by physicians who have improper financial relationships with other providers. In enacting the statute, Congress found that improper financial relationships between physicians and entities to whom they refer patients can compromise the physicians' professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied upon various academic studies consistently showing that physicians who had financial relationships with such entities used more of those entities' services than similarly situated physicians who did not have such relationships. The statute was designed specifically to reduce the loss suffered by the Medicare program due to such increased questionable utilization of services.

25. Congress enacted the Stark Statute in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. *See* Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204.

26. In 1993, Congress extended the Stark Statute (Stark II) to referrals for ten additional designated health services. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, § 13562, Social Security Act Amendments of 1994, P.L. 103-432, § 152.

27. As of January 1, 1995, Stark II applied to patient referrals by physicians with a prohibited financial relationship for the following ten additional "designated health services": (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics,

and prosthetic devices and supplies; (9) outpatient prescription drugs; and (10) home health services. See 42 U.S.C.§ 1395nn(h)(6).

28. In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then –
>
> The physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
>
> The entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn (emphasis added).

29. The Stark Statute broadly defines prohibited financial relationships to include any compensation paid directly or indirectly to a referring physician.

30. Violation of the statute may subject the physician and the billing entity to exclusion from participation in federal health care programs and various financial penalties, including (a) a civil money penalty of $15,000 for each service included in a claim for which the entity knew or should have known that payment should not be made under Section 1395nn(g)(1); and (b) an assessment of three times the amount claimed for a service for a service rendered pursuant to a referral the entity knew or should have known was prohibited. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

D. AFFECTED GOVERNMENT PROGRAMS

31. Medicaid is the nation's medical assistance program for the needy, the medically-needy, aged, blind, and disabled families with dependent children. See 42 USC §§ 1396-1396v. Medicaid is largely administered by the States and funded by a combination of federal and state funds. Approximately 57% of Medicaid funding is provided by the Federal Government on a national basis.

32. Medicare is the nation's health program for persons over sixty-five (65) years of age and the disabled. Medicare is funded by the Federal Government.

33. The Department of Veterans Affairs ("VA") provides medical assistance, including physician ordered drug testing, to persons who have been discharged from active duty service in the military, naval, or air services.

34. The Department of Defense ("DOD") administers the TRICARE health care program for active duty and retired members of the uniformed services, their families, and survivors.

E. THE MEDICARE PROGRAM

35. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. Part B of the Medicare Program authorizes payment for services or supplies that are needed to diagnose or treat a medical condition and that meet accepted standards of medical practice. CPS derived a substantial portion of its revenue from the Medicare Program.

36. Under the Medicare Program, the Federal government makes payments retrospectively (after the services are rendered) to providers on behalf of the eligible patients. Medicare enters into provider agreements in order to establish provider eligibility to participate

in the Medicare Program. However, Medicare does not prospectively contract with entities to provide particular services for particular patients. Any benefits derived from those services are derived solely by the patients and not by Medicare or the United States.

37. To participate in the Medicare program as a new enrollee, clinical laboratories, must submit a Medicare Enrollment Application, CMS Form-855B. Laboratories also complete Form CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

38. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

39. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program."

40. Necessary to its participation, CPS signed the certification statement in Section 15 of Form CMS-855B, acknowledging that the laboratory was required to comply with Medicare laws, regulations, and program instructions, which include, but are not limited to, the Stark Law and the Anti-Kickback Statute.

41. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

42. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent known as the 837P form. Among the information the provider

or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source."

43. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 13951(q)(1).

44. From 2011 to 2017, CPS processed Medicare claims under NPI number 1104854124, which was issued under the application submitted by CPS's president, Steven Reid Dickerson, M.D.

F. THE STATE MEDICAID SYSTEMS

45. Each of the states in which CPS does business has established a Medicaid Program authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. Each of the CPS states' Medicaid programs are required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a.

46. Medicaid handbooks are issued for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible Medicaid recipients.

47. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. "Medicaid Provider Enrollment Applications" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients. Under Section VII of the Application, in order to be eligible to receive direct or indirect payments for services rendered to Medicaid Program recipients, a provider must certify that the provider understands "that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws." The agreements between the providers and the state Medicaid programs also require certification and acknowledgement that the services provided, and for which reimbursement is sought, were medically necessary to the health of the patient.

G. REGULATIONS REGARDING COVERAGE FOR LABORATORY TESTS

48. Medicare and Medicaid regulations both make clear that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury, that laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services, and that claims for such services must be denied.

H. MEDICARE COVERAGE FOR LABORATORY TESTS

49. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), as set forth at 42 C.F.R. Part 493.

50. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the… examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (pub. 100-

02), Ch. 15, § 80.1, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (visited March 15, 2014).

51. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. See 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B…for any expenses incurred for items or services…which…are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]").

52. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary….[T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, Section 80.6.1.

53. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). MPBM, Ch.15, § 80.1.

54. In order to assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 13951(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation)….").

55. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)

56. CMS regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> (iii) ***Medical necessity.*** The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary.
> 42 C.F.R. § 410.32(d)(3).

57. Congress has not passed legislation permitting Medicare coverage for urine drug tests in the absence of signs or symptoms of illness or injury.

58. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998), available at https://oig.hhs.gov/authorities/docs/cpglab.pdf (visited March 15, 2015). Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered and that ***Medicare generally does not pay for***

tests for screening purposes and that ***standing orders (concerning screening) generally should not be used***:

> Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, including that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient.
> ...
> a. Requisition design: While HCFA [(CMS)] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill...
> **The form should contain a statement indicating that Medicare generally does not cover routine screening tests.**
>
> 4. Reliance on Standing Orders
> Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary... Medicare contractors can and may require additional documentation to support the medical necessity of the test. **As a result of the potential problems standing orders may cause, the use of standing orders is discouraged.**

Id. at 45079, 45081 (emphasis added).

59. The states in which CPS does business have adopted differing standards and definitions of what constitutes "medically necessary." However, at a minimum, each of those states requires that reimbursable services must be provided in conformance with commonly and customarily recognized standards of good practice, appropriate and consistent with the diagnosis or treatment of the particular patient's illness or injury, and reflecting an appropriate supply or level of service.

V. BACKGROUND: TYPES OF UDT, GUIDELINES, AND REIMBURSEMENTS

A. Types of Urine Drug Tests

60. Drug testing is used to determine the presence or absence of drugs or metabolites, also known as "analytes," in a patient's system. Drug testing can be "qualitative" (to determine the presence or absence of an analyte) or "quantitative" (to provide a numerical concentration of an analyte). Different testing methodologies have different capabilities and limitations.

61. Drug testing is performed in a number of contexts. Some workplaces have mandatory drug testing requirements, in some instances required by federal regulations. In the clinical health care context, drug testing can be used to monitor whether patients are taking prescribed drugs or taking or abusing drugs not prescribed.

62. Drug testing can be accomplished through analysis of a patient's saliva, blood or urine. The types of tests available present different advantages and can vary widely in associated cost.

63. The different types of drug testing also vary based on the location of the test (in-office or at a laboratory).

64. "Point of care" or "POC" testing—at a physician's office or clinic—is generally performed by "immunoassay" methodologies, which generally provide a qualitative result indicating the presence or absence of a drug or drug class above pre-set "cut-off" or concentration levels. In-office testing is often performed with POC drug test cups that have a number of built-in drug test strips, each of which tests for a specific drug or drug class. In-office testing can also be performed on immunoassay analyzer machines, known as "desktop" or "benchtop" analyzers, which are more sophisticated and generally reimbursed at higher levels than POC test cups.

65. Under CLIA, CMS oversees all laboratory testing services. UDT performed using POC drug test strips and test cups is generally "CLIA-waived." CLIA-waived tests are categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result or pose no risk of harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 42 C.F.R. §493.35. To operate a benchtop or desktop analyzer, physician practices are generally required to obtain CLIA certification to perform moderate- or high-complexity laboratory tests.

66. Since April 2010, Medicare generally only reimburses one unit of POC testing per patient encounter, based on the methodology used (analyzer versus POC test cup with embedded test strips). As of January 1, 2011, the Medicare reimbursement for POC tests is determined by the complexity of the test under CLIA (HCPCS billing code "G0434" for CLIA-waived tests and "G0431" for high-complexity analyzer test).

67. POC drug testing, including use of POC test cups, is the standard of practice for drug testing in pain management. Most patients need only limited, if any, laboratory testing, based on their POC test results, drug abuse history, and clinical presentation.

68. Testing at laboratories is generally performed by more precise methodologies, such as column chromatography in combination with mass spectrometry. Such methods include gas chromatography with mass spectrometry ("GCMS") and liquid chromatography with mass spectrometry ("LCMS"). These testing methodologies can provide quantitative results, identifying the *concentration* of a drug or metabolite in a sample. Quantitative tests are often billed for each drug or drug class tested, using CPT codes assigned for quantitative tests of each

drug or class and, in some cases, multiple units of those CPT codes. Quantitative tests can be used to "confirm" POC test results, as they use a second, more accurate methodology.

69. CPS performed UDT by liquid chromatography with tandem mass spectrometry ("Mass Spec" or "LC-MS/MS").

70. LC-MS/MS technology enabled CPS to test urine specimens for numerous drugs and metabolites during a single run of an aliquot of a urine sample through the LC-MS/MS machine.

B. Expected versus Unexpected POC Test Results

71. The clinical value of a "confirmatory" or "quantitative" laboratory testing depends on a patient's medical condition. The clinical utility of a "confirmation" or "quantitation" of POC test results depends in part on whether the POC test result is expected or unexpected, and the patient's drug abuse history and clinical presentation.

72. For example, if a patient is prescribed a certain drug, such as Xanax, a positive POC test result for benzodiazepines (of which Xanax is one) would be expected. If the test result is negative for benzodiazepines, however, and the patient insists that she is taking her Xanax as prescribed, a quantitative laboratory test to "confirm" whether this unexpected negative result may be reasonable and necessary.

73. Similarly, if a patient's POC test yielded a positive result for a non-prescribed or illicit drug, then a quantitative laboratory test to evaluate (i.e., "confirm") this unexpected positive result may be reasonable and necessary.

74. In some instances, laboratory testing of an expected POC test result or for a substance not available on a POC test may also be warranted. For example, aberrant patient behavior, unexpected clinical presentation, or a history of drug abuse may justify specific

laboratory tests. The clinical value of such tests, however, depends on the presentation and physician assessment of each individual patient and that patient's need for each such test. If a POC test is negative for an illicit drug or drug not prescribed, and there is nothing in the patient's presentation or drug abuse history to indicate abuse of that drug, then a quantitative laboratory test for that drug is not reasonable and necessary for the treatment and diagnosis of that patient, and therefore not covered by Medicare.

C. Guidelines on Urine Drug Testing

75. Several organizations have published guidelines regarding UDT in the clinical setting, including UDT for chronic pain patients prescribed opioids. According to the Substance Abuse and Mental Health Services Administration ("SAMSHA"), the development of UDT guidelines in the clinical setting draws on the experience of workplace drug testing, including the Federal Drug-Free Workplace Program and its guidelines ("Federal Workplace Guidelines"). 73 Fed. Reg. 71858 (Nov. 25, 2008).

76. Under the Federal Workplace Guidelines, a "negative Result" includes results reported by certified laboratories when a valid specimen "contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class." *Id.* At 71878 (Sec. 1.5). Laboratories may report a valid specimen as "negative" when "each initial result on these initial immunoassay tests do not require confirmation testing by another method. *See id.*

77. As CPS knew, none of these guidelines recommended the routine use of quantitative laboratory testing, such as the LC-MS/MS testing that CPS performs, to "confirm" expected negative immunoassay results.

78. Instead, when these guidelines addressed the need for confirmatory/quantitative laboratory testing, they generally recommended a UDT protocol whereby an immunoassay test is

administered first and then only *unexpected* results are referred for laboratory-based confirmatory testing via a quantitative method such as LC-MS/MS.

D. Reimbursements for Laboratory Tests

79. Different types of urine drug tests have different costs.

80. Since January 2011, POC test cup tests have been billed to Medicare using HCPCS code G0434 and reimbursed at a fixed rate of approximately $20-25 per patient encounter—regardless of the number of substances tested. Also since January 2011, POC high-complexity immunoassay tests have been billed to Medicare using HCPCS code G0431 and reimbursed at a fixed rate of approximately $100 per patient encounter—again, regardless of the number of substances tested.

VI. BACKGROUND: GENETIC TESTING FOR PAIN MANAGEMENT PATIENTS

81. A small percentage of the general population metabolizes pain medication differently due to their genetic make-up. A rare variation in enzymatic metabolism, dictated by genetic makeup, can cause either poor or ultra-rapid metabolization.

82. Cytochrome P450 (CYP450) is a group of liver enzymes that aid in the metabolism of approximately ninety percent (90%) of all pharmaceutical drugs. There are numerous enzymes in the CYP450 systems that are involved in the metabolism of many commonly prescribed drugs.

83. CYP2D6 is the hepatic enzyme involved in metabolism of several opioids. This uncommon genetic variation influences the metabolism of drugs prescribed for pain management and is present in only a small percentage of the patient population.

84. Genetic testing may be indicated on a small percentage of patients population who have poor or no response to pain medication, but there is no research to date showing the need or

clinical benefit for early or routine genetic testing of the cytochrome enzyme system in pain management patients.

85. A 2013 study published in Journal of Pain concluded that current research is insufficient to individualize opioid treatment for chronic pain patients based upon personal characteristics including genetic testing. Bruehl, Stephen, Apkarain Vania A., et. Al. "Personalized Medicine and Opioid Analgesic Prescribing for Chronic Pain: Opportunities and Challenges" Journal of Pain. 2013; 14(2): 103-113. On page 106 of the article, the authors specifically addressed the necessity of genetic testing on pain management patients, as follows: "Although these findings are clinically intriguing, genetic data necessary for developing personalized analgesic prescribing protocols are currently lacking."

86. As such, routine genetic testing on all pain management patients has no proven clinical benefit and is not medically necessary as a general rule.

VII. DEFENDANTS' FRAUDULENT SCHEMES

87. During the relevant period, CPS conducted its business through pain management clinics operated in at least twelve states: Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Ohio, Tennessee, and Virginia. CPS has financial relationships with at least 35 physicians, most of whom CPS classified as independent contractors. CPS also had financial relationships with over 100 nurse practitioners, most of whom CPS classified as employees.

88. In an effort to circumvent the prohibitions of the AKS and the Stark law, CPS established a multi-state coalition of physicians and pain clinic centers under an attempted "group-practice." The group practice was expected and required to refer all patients to the company's labs and pharmacies. The physicians would bill the services provided by their

"supervised" nurse practitioners and physician assistants as "incident to" the physicians' personally provided pain clinic services, regardless of the extent to which, or even whether, the physicians personally interacted with the patients on the date of service.

89. CPS has one NPI identifier through which it bills Medicare for allegedly eligible services and products regardless of which location or physician provided the services rendered or prescribed the medicine. These include all services provided at CPS's off-site drug screening lab and compound pharmacy.

90. CPS established a strategy to increase profits by exploiting the health care insurance and medicare system through systematic submission of payment claims for grossly unnecessary and repetitive in-patient consultations and drug screenings. The company centered its practice around an off-site clinical laboratory, available for referrals from all of the affiliated clinics. Central to its business model is CPS's wholly owned off-site screening laboratory and compound pharmacy. CPS requires and incentivizes its physicians and nurse practitioners to refer all patients for services and products created and provided at these off-site locations.

91. CPS knew that its employment, compensation, and screening schemes were illegal. CPS nonetheless recruited and pressured its employees into participating in these schemes by fostering a culture of greed, intimidation, and intense sales pressure. At the heart of CPS's recruiting pitch to physicians is the promise that they would share significantly in the revenues generated by their referrals and those of their "supervised" nurse practitioners.

92. CPS's physicians were generally hired as independent contractors for the specific purpose of serving as "pain management and medical director[s]." The physicians' contracts provided that they were responsible for the medical treatment provided to "each person who comes into the clinic." These physicians were instructed and greatly incentivized to refer

patients to CPS's ancillary services and laboratory, and were paid compensation for doing so. Additionally, as an inducement and to incentivize the physicians to generate nurse practitioner referrals, the physicians were offered, and were paid, compensation based on the revenue collected by the nurse practitioners considered to be under their supervision.

93. CPS's physicians' regular income was calculated by a formula that included a percentage of all "revenue" "collected" by nurse practitioners and physician assistants considered to be "under the supervision" of the physician. No exception was made for revenues collected through Federal health care programs, such as Medicare. CPS's physicians also would receive a bonus determined in accordance with their share of collections for clinical laboratory services and other designated health services. The physicians were also paid bonus compensation that was based on revenue generated by their supervised nurse practitioners and nurse assistants, who were being paid kickbacks as incentives to make the referrals. This arrangement was ineffectively, but intentionally, designed to skirt the prohibitions of the Anti-Kickback and Stark laws, which were enacted to prevent the precise abuses in which the Defendants have been engaged.

94. The physicians with whom CPS had improper financial relationships, and to whom CPS paid remuneration based on the number and types of referrals for ancillary services made by the physicians and their supervised nurse practitioners included, but may not be limited to:

Dr. Daniel McHugh
Dr. Aaron Carter
Dr. Albert Singh
Dr. Barbara Schooley
Dr. Benjamin Cameransi
Dr. Christopher Middendorf
Dr. Dennis Harris
Dr. Donald Jones

Dr. Dwight Mosley
Dr. Edwin Dunteman
Dr. EJ Oddono
Dr. Eric Young
Dr. Frank Jordan
Dr. James Ladson
Dr. Jeff Hall
Dr. Michael Danko
Dr. Nabil Ahmad
Dr. Nancy Faller
Dr. Paul Pinson
Dr. Randy Underwood
Dr. Raymond Greaser
Dr. Rex Williams
Dr. Ron Williams
Dr. Ruther Anderson
Dr. Stuart Gross
Dr. Suzanne Alt
Dr. Thomas Brummett
Dr. Timothy Beacham
Dr. Todd Pepper
Dr. William J. Martin
Dr. Wynndel Buenger
Dr. Gilberto Carrero
Dr. Peter Kroll
Dr. Richard Muench
Dr. Steven Dickerson

95. Most of the CPS patient encounters occurred through CPS's employed nurse practitioners. These nurses were generally licensed to make diagnoses and prescribe treatment on their own, but CPS had all, or substantially all, of their services and referrals coded as "incident to" the care and attendance of their on-site supervising physician. The reason for this, as CPS officials admitted, was so that CPS could bill the nurses' services at 100% of the reimbursable rate, whereas NP services that were not so designated reimbursed only at 85%. The nurses contracts did not require that they make referrals to CPS's labs or pharmacy, or to even encourage patients to use CPS's ancillary services. The contracts included vague references to bonus eligibility, but there were no terms included in the contract, other than

assurance that the nurses would "be eligible for bonuses as determined from time to time in the discretion of Employer." As such, the nurses' employment was not expressly conditioned on the referral of ancillary services, and they were not contractually obligated to make such referrals as a condition of their employment.

96. Separate and apart from the nurses' employment contracts, CPS developed a schedule of "bonusable items" which identified kickback amounts for specified referral services and products offered by CPS. The subject services and products, and the amounts to be paid to the nurse practitioners for such referrals, were recorded as follows:

- TENS UNIT DISTRIBUTED- $25
- TENS PADS FOR NON MEDICARE AND NON MEDICAID - $10
- LSO L0631 or L0637 DISTRIBUTED - $50 (Back braces)
- LSO L0627 DISTRIBUTED - $25 (Back brace)
- KNEE BRACE DISTRIBUTED - $50
- UDS FOR NON MEDICARE / NOT INCLUDING HEALTHSPRING, BLUECARE OR SELF-PAY - $10
- EMG IN HOUSE UPON COMPLETION OF TEST - $30
- ULTRASOUND PER PROCEDURE - $25
- SCS (Spinal Cord Stimulator) TRIAL IN OFFICE UPON COMPLETION OF SERVICE - $150
- RADIOFREQUENCY - $25 PER SIDE COMPLETED IN CPS CLINIC
- OCCIPITAL NERVE BLOCK - $25
- SLEEP STUDY FOR MEDICARE - $10 – COMPLETED AND CHARTED
- SLEEP STUDY FOR NON-MEDICARE IN HOME - $25 – COMPLETED AND CHARTED
- TRIAMCINOLONE A - $25 (Any injection or procedure performed under your progress / procedure note – does not include if MD performs procedure)
- IPAD PSYCH TESTING $5 (TRACKED THROUGH ECW/CPS)
- WELLNESS/HORMONE BLOOD PANEL $25 (TRACKED THROUGH ECW/CPS)
- GENETIC BLOOD PANEL $25 (TRACKED THROUGH ECW/ CPS)
- P-STIM $25/FITTING
- COMPOUNDED CREAM FILLED AND SHIPPED FROM CPS PHARMACY FOR PRIVATE INSURANCE $25/FILL
- COMPOUNDED CREAM FILLED AND SHIPPED FROM CPS PHARMACY FOR MEDICARE (or SF-03 fills) $10/FILL

97. Though urine drug screens (UDS) for Medicare patients were not included among the expressly listed bonusable items, CPS COO Shannon Skipper assured nurse practitioners that they would be paid $5.00 for each Medicare patient's urine drug screen.

98. As CPS knew, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for ***each test*** for ***each patient*** must be individually assessed and documented in the patient's medical chart. 42 C.F.R. §§410.32(a), (d)(2). Many patients, including those with chronic pain, do not need extensive laboratory-based UDT. CPS nonetheless sought to, and did, cause its clinicians to routinely and frequently order extensive and expensive UDT for all of their patients in order to make more money. CPS then billed Medicare for each drug or drug class tested-including tests for drugs that patients were not suspected of taking. CPS did not allow in-office screening, known as "point of care" or "POC" testing, but instead required all drug screens to be sent to the CPS lab.

99. In order to maximize the income generating potential of CPS's lab, CPS issued notices to all of its health care providers establishing a written protocol requiring all new patients to undergo urine drug screening, and to have follow-up testing "every 8 weeks." Though this would have been excessive and medically unnecessary as written, CPS's actual practice and procedure required all patients to provide urine specimens on a monthly basis. CPS instructed its physicians and nurse practitioners to reschedule monthly follow up visits. Upon each visit, each patient was instructed to provide a urine sample before being seen by a practitioner. CPS instructed its physicians and nurse practitioners to submit each urine sample to CPS's lab for screening.

100. CPS's urine drug screens were overly comprehensive and not tailored to the individual patient. Virtually all specimens sent to CPS's drug screening labs from any given CPS clinic were subject to essentially the same quantitative UDT panel, regardless of the patient's presentation, demographic profile, medical history, or history of drug or alcohol abuse.

101. In fact, *prior* to any clinician actually seeing a patient, CPS imported a uniform template description of the patient's medical necessity for the UDS. The template provided as follows:

> Clinical Notes: UDS Collected: Urine sample was collected and sent to lab for screening (THC, BARB, EtG, pH, SPEC GRAVITY, Oxidants, Cr) and confirmation testing via LCMS (Benzodiazepines with break down, barbituates, marijuana, opioids with breaks down, synthetic opioids, cocaine, carisoprodol, amphetamine and methamphetamine). The patient meets criteria for low risk of opioid misues, abuse or diversion. However due to the chronicity of the patient's opioid needs the UDS is done to monitor opioid use and ongoing candidacy; verify compliant use of controlled substances, long-term/ chronic use, and ensure no illicit use.

102. In addition to the written protocol, CPS health care providers were instructed verbally to have each patient return *every month* for follow-up visits, and to have the patient undergo urine drug screening *every month*. CPS reminded the nurses and the physicians that adherence to, or disregarding of, these instructions would directly impact their income.

103. In addition to pressuring the physicians and nurse practitioners to over screen, CPS also pressured the patients by, among other methods, designing patient agreements that suggested that *the patient* was required to comply with the monthly regimen, and that failure to do so would result in the patient losing his care providers. Specifically, the CPS patient forms required each patient to acknowledge that

> any follow-up appointment may be scheduled with a Licensed Nurse Practitioner or Physician Assistant. . . . I understand that

> refusing to see one of CPS providers will likely result in my no longer being able to be treated at the practice. . . . I understand that I may be released from CPS for missing appointments . . .

Failure to submit the monthly-required urine samples was also cause for dismissal from the patient's treatment program:

> I understand that CPS providers utilize tests to determine the best option for my care. My unwillingness to complete the tests requested may result in being released from further care with CPS.

104. CPS's patient information sheet suggested that the patient might be required to "submit to a blood, urine or saliva test . . . to determine *compliance* with my program of pain medication." Notwithstanding the availability of other competent and less expensive on-site drug testing compliance alternatives, CPS falsely suggested to its physicians and nurse practitioners that such alternatives were generally improper and/or legally prohibited.

105. CPS discouraged the use of narrow, focused drug screens tailored to the individual patient's situation. *Vis a vis* the much cheaper alternative saliva test, CPS instructed its providers that "urine is *always* the preferred specimen – it is the most tested and validated and provides consistency with which *we treat all of our patients."* Consistently, CPS instructed and expected that saliva tests should almost never be used, expressly prohibiting its use except only for "patients who are not *able* to provide urine . . ."

106. Within the same guidelines, CPS also mandated the use of CPS's captive screening lab, and prohibited the use of less costly on-site alternative urine testing procedures, suggesting that a violation of this rule would result in "excessive" "penalties."

> Currently, there are to be NO in clinic testing of urine samples beyond the temperature strips on the designated urine cups. ALL point of care testing (POCT) MUST be performed by a CLIA waived regulated lab. *The clinic regulations for CLIA waived requirements are currently not conducive to our current clinic*

> *model.* There are to be NO exceptions to make clinical decisions based upon POCT for any clinic as the *penalties are excessive*.

107. These were misrepresentations intended to deceive the clinicians and to justify CPS's fraudulent business goals. Indeed, there was nothing about the individual clinics that prevented the physicians from applying for, or receiving, CLIA waivers for point of care testing. And CPS intentionally did not inform its providers that most of the alternative POCT methods either did not require waivers or that CPS never applied for such waivers for its clinics.

108. Understandably, CPS providers rarely used any drug testing methodology other than what CPS referred to as the "gold standard" LC/MS – Liquid Chromatography/Mass Spectrometry drug screening conducted at the off-site laboratory. It was – and is – a money making machine. When Relator Scott Steed toured the facility with members of CPS's executives, the overpowering and unpleasant smell of urine was observed. In response CPS's COO Shannon Skipper responded, "To me, it smells like money."

109. Indeed, CPS billed and received from Medicare millions of dollars for laboratory UDT. But most of these screens tested for substances that were not relevant to the patients' care, and for which abuse is virtually non-existent in the Medicare patient population. Most of CPS's tests consisted of follow-up testing on results that were consistent with clinical expectations, offering very little, if any, clinical value at great expense to Medicare.

110. CPS also instructed its nurse practitioners to conduct "Health and Wellness Panels" once a year, which included hormone testing, glycated hemoglobin testing for diabetes, a comprehensive metabolic panel, and a complete blood count. Many of the components tested did not relate to the patient's care, yet were required as standard tests. Initially, CPS requested that these tests be performed once a year, CPS now requires these tests multiple times a year.

111. Similarly, CPS also instructed its physicians and nurse practitioners to conduct "genetic testing" on each of its new patients – before any pain medication was even prescribed, and before there was any indication that the patient was not responding to prescribed medication.

112. In order to induce the physicians and nurse practitioners to order routine genetic screening, CPS communicated false and misleading information. Specifically, on or about August 15, 2014, and in supplementation to other prior misleading information, CPS Chief Operations Officer Jeff Hurst stated to all CPS clinic staff – including all CPS physicians and nurse practitioners, that "genotyping tests, such a cytochrome P450, help identify medications that will be more effectively metabolized by the body [which leads to] fewer side effects and improved effectiveness." Mr. Hurst went on to encourage initial genetic testing in order to properly "classify" the patients by their ability to metabolize, i.e., as "poor," "intermediate," "normal," or "ultrarapid" metabolilzers.

113. CPS failed to inform its physicians and practitioners that genetic screening was not indicated for all patients, and that it should not be used as a general practice. To the contrary, CPS physicians and nurse practitioners were instructed, expected, and paid to use genetic testing as part of a default "comprehensive" plan of pain management.

114. In response to CPS's polices and communications, CPS physicians and nurse practitioners prescribed and referred its patients for front-line genetic screening tests performed by CPS. CPS, in turn, performed these tests, billed government programs for the services, and received substantial payments in return. In addition, CPS paid kickbacks and remuneration to its nurse practitioners and physicians in direct response to the genetic testing referrals, all in violation of federal law.

115. CPS's aggressive screening and follow-up protocols caused its patients to incur regular co-pay obligations and unnecessary charges, regardless of whether the services were medically necessary. Medicare patients were required to contribute "co-pay" amounts for the amounts billed to Medicare and were also held financially responsible for any services that were not covered by their respective plans. CPS's patient information sheet represents that "the practice will NOT waive or fail to collect any co-payments . . . or other patient financial responsibility in accordance with state and federal law . . ." and that "any patient balances that remain delinquent after 90 days, with no response to requests, payment, may be referred to a collection agency."

116. CPS's patients were not given a choice as to the type of tests which could have been performed, or the relative costs of same, or how frequently the screens should occur. As a result of the high frequency of in-office patient visits, many of CPS's patients complained to CPS of the accumulating costs and debt associated therewith. If the patients did not pay the co-pays when they were billed, CPS instituted collection efforts. However, CPS instructed its staff and medical providers that if any CPS customer complained about the collection efforts, the patient was to be assured that they would not have to pay the accumulated debt as it pertained to the UDS billing.

117. CPS's pain management treatment also included prescription of creams and topical agents that required specialized production from a compound pharmacy. CPS funneled all prescriptions for such medicines to its own compound pharmacy by informing patients that the prescriptions would be filled by CPS. CPS's computer systems did not identify other available compound pharmacies for "e-submission," and CPS would only permit prescription to other pharmacies if the patient requested the ability to do so, which rarely occurred.

121. Periodically, CPS would communicate concerning the frequency with which each of its clinics was utilizing the "bonusable items." CPS would remind all its clinicians that their monthly and/or quarterly bonuses depended on the numbers of ancillary services and products that were being referred. For example, on March 24, 2015, CPS CEO John Davis informed "everyone" that CPS encourages use of all available therapy options, and that it was "not acceptable" that certain clinics were not using one of the "encouraged" tools of CPS's "comprehensive" screening methods – IPAD psych evaluations.[1] As a result of those clinics who were using this particular method "sparingly" or "NONE," Mr. Davis warned that "the quarterly bonus will be negatively affected." This theme was repeated on March 25, 2015, when CPS's "Director of Clinician Education," Sarah Trent, observed that "doing all that we can . . . to protect our patients" has the added benefit of "protect[ing] our livelihood." In this regard, Ms. Trent reminded all CPS nurse practitioners and physicians that "utilizing any of the resources that CPS makes available to us in managing our patients comprehensively [specifically referencing "use of urine drug screens"] does assist with your bonus at the quarterly true up – however, failure to be comprehensive in your approach to patient care can negatively impact this."

118. As a result of the foregoing schemes, CPS knowingly submitted and caused to be submitted false claims to Medicare and Medicaid for services that were neither reasonable nor necessary. CPS also made false and misleading statements about the need for and value of its drug testing services to encourage such testing, and paid physicians and nurse practitioners remuneration -- tied to physician referrals—to secure and generate referrals and get them to agree to high levels of testing.

[1] The IPAD testing is now being conducted monthly.

CONSPIRACY TO PAY AND RECEIVE KICKBACKS FOR ILLEGAL PATIENT REFERRALS

119. As discussed herein, the defendants agreed to establish financial relationships, and entered into agreements, the primary elements of which were: (i) that CPS would make certain payments to its referring physicians for the purpose of inducing such physicians to refer Medicare and Medicaid patients for CPS reimbursed services, (ii) CPS would make certain payments to nurse practitioners, for the purpose of inducing such nurse practitioners to refer Medicare and Medicaid patients for CPS reimbursed services and for the purpose of increasing the income to be paid to CPS's physicians; (iii) CPS and its financially related providers would agree to schedule patients for monthly visits and require those patients to submit urine specimens for comprehensive monthly urine tests conducted at CPS's laboratory; (iv) CPS would create and submit default justification for each patient suggesting that each patient's services were "incident to" the physician's personal care and medically necessary when in fact treatment and screening plans were not individually tailored; and (v) CPS would in fact submit claims for payment to Medicare and Medicaid for such patients. Such agreements benefited CPS, since it ensured a steady stream of referrals for Medicare and Medicaid patients, who might not otherwise have been referred to CPS, and certainly not in the frequency to which such referrals would be made. Such agreements also benefited CPS's physicians, its physician investors, and CPS's nurses, since they received payments and other valuable benefits from CPS greater than they would have received absent such agreements.

STARK LAW SELF REFERRALS

120. During the period from 2011 through 2017, CPS maintained significant "financial relationships" with approximately 35 physicians and 100 nurse practitioners by providing salary

and bonuses pursuant to contracts and service agreements. These relationships were coordinated by, or arranged through, CPS and its management.

121. During the period from 2011 through 2017, CPS physicians and nurse practitioners referred thousands of patients to CPS for on-site clinical services and off-site ancillary services. These were referrals within the meaning of the Stark Law.

122. CPS knowingly presented or caused to be presented claims to Medicare, Medicaid and other government programs for designated health services pursuant to referrals referred to in the preceding paragraphs in violation of 42 U.S.C. § 1395nn (a)(1)(B).

KICKBACKS TO PHYSICIANS AND NURSE PRACTITIONERS FOR ILLEGAL PATIENT REFERRALS

123. From 2011 to 2017, CPS "willfully offer[ed] [and paid] remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." During the same time period, CPS's physicians and nurse practitioners "willfully . . . receiv[ed] remuneration . . . indirectly . . . in cash . . . in return for referring an individual . . . for the furnishing of . . . item[s] [and] service[s] for which payment may be made in whole or in part under a Federal Health Care program."

SUBMISSION OF CLAIMS

124. CPS submitted thousands of claims to federal government programs, including Medicare and Medicaid, for patients referred by CPS and its investors as a result of the kickbacks, improper financial relationships, and policies directing the provision of medically unnecessary services, as discussed above. For example,

On March 10, 2014, patient SP received a Pulse Stimulation Treatment at CPS' Flowood clinic location. The charge for this service was billed to Medicare and qualified as a bonusable item, for which Relator Kimbrough was paid $25. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Ron Williams;

On September 2, 2014, patient EH received TENS Unit and Pads at CPS' Flowood clinic location. The charge for this service was billed to Medicare and qualified as a bonusable item, for which Relator Kimbrough was paid $25. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Ron Williams;

On September 3, 2014, patient LB received a Urine Drug Screening Test and a Health and Wellness Exam at CPS' Flowood clinic location. The charge for this service was billed to Medicare and qualified as a bonusable item, for which Relator Kimbrough was paid $30. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Williams;

On August 6, 2014, patient BM received Health and Wellness Exam and Urine Drug Screen Test at CPS' Flowood clinic location. The charge for this service was billed to Medicare / Medicaid and qualified as a bonusable item, for which Relator Kimbrough was paid $25. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Ron Williams;

On October 8, 2014, patient CH received Urine Drug Screen Test at CPS' Flowood clinic location. The charge for this service was billed to United Medicaid and qualified as a bonusable item, for which Relator Kimbrough was paid $5. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Williams;

On August 25, 2014, patient AS received a Health and Wellness Exam, Urine Drug Screening Test, Stellate Ganglion Block Injection at CPS' Flowood clinic location. The charge for this service was billed to Tricare Standard and qualified as a bonusable item, for which Relator Kimbrough was paid $55. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Ron Williams;

On October 8, 2014, patient RS received a Urine Drug Screen Test at CPS' Flowood clinic location. The charge for this service was billed to Tricare and qualified as a bonusable item, for which Relator Kimbrough was paid $5. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Williams;

On September 3, 2014, patient DF received a Urine Drug Screen and Health and Wellness Exam at CPS' Flowood clinic location. The charge for this service was billed to Consolidated Fee Unit VA Vets and qualified as a bonusable item, for which Relator Kimbrough was paid $30. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Williams;

On January 7, 2015, patient JS was prescribed Comp. Cream from CPS' Flowood clinic location. The charge for this service was billed to VA Medical and qualified as a bonusable item, for which Relator Kimbrough was paid $10. The amount collected for this service was also credited as "revenue collected" by Ms. Kimbrough for purposes of determining the amount of compensation to be paid Dr. Williams.

125. Although Relators do not have reasonable pre-discovery access to the specific billing records for such claims, CPS is fully aware of the claims at issue.

THE KNOWLEDGE OF CPS THAT ITS ACTIONS WERE UNLAWFUL

126. During the time period relevant hereto, CPS, and its management, were aware of the prohibitions against kickbacks, the legal restrictions on financial relationships with physicians, and the legal requirements related to medically necessary services, including laboratory testing. In recruiting its physicians, and in negotiating and offering and to pay physicians, CPS managers expressly mentioned the Stark Act, and falsely explained that their payment arrangements effectively complied with the federal law.

127. CPS was also aware of *qui tam* litigation against a competitor drug screening service, Millennium, and even used the fact that sanctions had been imposed on Millennium to identify an opportunity for more business. In CPS's urine drug screen guidelines, CPS mentioned Millennium specifically, noting that Millennium (who had been scrutinized for almost identical fraudulent practices) was no longer allowed to conduct urine drug screens. CPS noted the competitive advantage this presented due to the fact that Millennium "can only run saliva samples."

128. Despite CPS's awareness that its practices were in violation of Federal law, CPS created and expanded its primary strategy of inducing patient referrals by paying kickbacks to physicians and nurses and engaging in unlawful financial relationships. CPS in turn billed for and collected millions of dollars in reimbursement from the United States and the States based upon patient referrals from these same physicians.

DAMAGES

129. The United States and all of the states in which CPS did business were damaged because of the acts of CPS in submitting, causing to be submitted, or conspiring to submit false

claims, statements and records in that these governmental entities paid CPS for items and services for which they were not entitled to reimbursement.

CAUSES OF ACTION

COUNT I

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

130. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

131. CPS knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States, including claims for reimbursement for services rendered to patients unlawfully referred to CPS by physicians to whom defendants provided kickbacks and/or illegal remuneration and/or with whom defendants entered into prohibited financial relationships in violation of the Anti-kickback Statute and/or the Stark Statute.

132. CPS knowing presented or caused to be presented false or fraudulent claims for payment or approval to the United States, including claims for reimbursement for services rendered to patients that were not reasonable or necessary.

133. By virtue of the false or fraudulent claims made by the defendants, the United States suffered damages.

COUNT II

(False Claims Act: Making or Using False Record
or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729 (a)(2))

134. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

135. Defendants knowingly made, used, or caused to be made or used, false records or statements – *i.e.,* the false certifications and representations made or caused to be made by

defendants when initially submitting the false claims for interim payments and the false certifications made or caused to be made in the Medicaire Enrollment applications required for laboratory testing, and otherwise.

136. By virtue of the false records or false statements made by the defendants, the United States and the States suffered damages and therefore are entitled to treble damages and penalties.

COUNT III

(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))

137. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

138. Defendants knowingly made, used, and caused to be made or used, false records or statements — i.e., false statements regarding compliance and coverage for its services and false statements on forms required to get false or fraudulent claims paid and approved by the United States.

139. Defendants' false certifications and representations were made for the purpose of inducing physicians to order its services and getting false or fraudulent claims paid, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendant's statements and actions.

140. The false certifications and representations made and caused to be made by Defendants were material to the United States' payment of the false claims.

141. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT IV

(False Claims Act; Conspiring to Submit False Claims)
(31 U.S.C. § 3729(a)(3))

142. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

143. Defendants entered into agreements with certain physicians and conspired to defraud the United States by submitting false or fraudulent claims for reimbursement from the United States for monies to which they were not entitled, in violation of 31 U.S.C. § 3729(a)(3). As part of schemes and agreements to obtain reimbursement from the United States in violation of federal laws, defendants conspired to provide kickbacks and illegal remuneration to physicians and to engage in prohibited financial relationships with physicians in violation of the Anti-kickback Statute and/or the Stark Statute, and to cause the United States to pay claims for health care services based on false claims and false statements that the services were provided in compliance with all laws regarding the provision of health care services whereas they were not so provided.

144. By virtue of Defendants' conspiracy to defraud the United States, the United States and the States suffered damages.

COUNT V

(Payment by Mistake)

145. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

146. This is a claim for the recovery of monies paid by the United States and the States to CPS as a result of mistaken understandings of fact.

147. The United States and the States paid CPS for services that were not reasonable and necessary for the diagnosis or treatment of individual patients as required under Medicare coverage rules, and that were furnished pursuant to prohibited referrals from physicians who were in financial relationships that did not comply with the Stark Law and/or the Anti-Kickback Statute, without knowledge of material facts and under the mistaken belief that CPS was entitled

to receive payment for such claims when it was not. The United States' mistaken belief was material to its decision to pay CPS for such claims. Accordingly, CPS is liable to make restitution to the United States and the States of the amounts of the payments made in error.

COUNT VI

(Unjust Enrichment)

148. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

149. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

150. By directly or indirectly obtaining government funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States and the States.

COUNT VII

Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1), (2), and (7)

151. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

152. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

153. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

154. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

155. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the Illinois State Government.

156. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

157. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT VIII

Indiana False Claims And Whistleblower Protection Act
IC 5-11-5.5-2(b)(1), (2), and (6)

158. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

159. This is a claim for treble damages and penalties under the Indiana False Claims And Whistleblower Protection Act.

160. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

161. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

162. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the Indiana State Government.

163. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

164. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

165. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every violation alleged herein.

COUNT IX

Iowa False Claims Act
Iowa Code § 685.1 et seq.

166. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

167. This is a claim for treble damages and penalties under the Iowa False Claims Act.

168. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Iowa Government for payment or approval.

169. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Iowa to approve and pay such false and fraudulent claims.

170. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the Iowa State Government.

171. The State of Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

172. By reason of the defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

173. Additionally, the State of Iowa is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT X

North Carolina False Claims Act
NC Gen. Stat. § 1-605 et seq.

174. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

175. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

176. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina Government for payment or approval.

177. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of North Carolina to approve and pay such false and fraudulent claims.

178. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the North Carolina State Government.

179. The State of North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

180. By reason of the defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

181. Additionally, the State of North Carolina is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

COUNT XI

Tennessee False Claims Act and Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a) and 71-5-182(a)(1)

182. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein..

183. This is a claim for treble damages and penalties under the Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

184. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

185. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

186. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the Tennessee State Government.

187. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

188. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

189. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

COUNT XII

Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1), (2), and (7)

190. Plaintiffs repeat and reallege all foregoing paragraphs as if fully set forth herein.

191. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

192. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

193. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

194. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, or decrease an obligation to pay money to the Virginia State Government.

195. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

196. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

197. Additionally, the Virginia State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

Judgment in an amount equal to treble the damages to be proven at trial against each Defendant and in favor of the United States, plus a civil penalty of up to $11,000 for each violation of 31 U.S.C.§ 3729 proven at trial;

Judgment in amount of proven damages at trial for payment in mistake of fact and unjust enrichment;

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat.§ 175/3 proven at trial.

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proven at trial;

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Iowa, plus a civil penalty of at least $10,000 for each violation of the Iowa False Claims Act proven at trial as well as costs as permitted by statute;

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of North Carolina, plus a civil penalty of $11,000 for each violation of N.C.G.S.A.§ 1-606 proven at trial;

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann.§ 71-5-182 proven at trial;

Judgment in an amount equal to treble the damages to be proven at trial against Defendants and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va Code Ann. § 8.01-216.3 proven at trial;

An award to Relators of the Maximum amount allowed pursuant to 31 U.S.C.§ 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees;

All such other, further and different relief, whether preliminary or permanent, legal, general or equitable, as the Court deems just and proper.

RESPECTFULLY SUBMITTED, this the 1st day of May, 2017.

By: _____

O. Stephen Montagnet, III (MSB# 10049)
Attorney for Relators

OF COUNSEL:

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